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K132509
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510(k) Summary

FDR D-EVO Flat Panel Detector System (DR-ID600)

Date: November 25, 2013

Submitter's Information:

FUJIFILM Medical Systems U.S.A., Inc.
419 West Avenue
Stamford, CT, 06902, USA

Contact Person:

Name: Katherine Y. Choi, RAC
Title: Regulatory Affairs Lead
Telephone: (203) 602-3568
Facsimile: (203) 602-3785

Identification of the Proposed Device:

Proprietary/Trade Name:	FDR D-EVO Flat Panel Detector System (DR-ID600)
Classification Name:	Stationary x-ray system
Regulations Number:	21 CFR 892.1680
Product Codes:	90 MQB
Device Class:	Class II
Review Panel:	Radiology
Common Name:	Flat Panel Digital Detector

I. INDICATIONS FOR USE

The Wireless/Wired FDR D-EVO flat panel detector system is intended to capture for display radiographic images of human anatomy. It is intended for use in general projection radiographic applications including pediatric and neonatal exams wherever conventional film /screen or CR systems may be used. The FDR D-EVO is not intended for mammography, fluoroscopy, tomography, and angiography applications.

II. DEVICE DESCRIPTION

Fujifilm's FDR D-EVO Flat Panel Detector System (DR-ID600) is a portable digital detector system that acquires and digitizes x-ray exposures from standard radiographic systems. It is designed to be used in any environment that would typically use a radiographic cassette. It can be placed in a wall bucky for upright exams, a table bucky for recumbent exams, or removed from the bucky for non-grid exams.

The FDR D-EVO FPD system is currently indicated for general projection radiographic applications and offers two different detector types in terms of scintillator materials (gadolinium oxysulfide (GOS) and cesium iodide (CsI)). The new submission is being submitted for the same FDR D-EVO FPD system to seek the clearance of the pediatric indication for use.

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Fujifilm Medical Systems, USA

III. SUMMARY OF STUDIES

The subject device, FDR D-EVO FPD system (DR-ID600) conforms to the voluntary standards such as IEC60601-1, IEC60601-1-1, IEC60601-1-2, IEC60601-1-4, UL60601-1 and DICOM. The newly adapted standardized dose index, Exposure Index (EI) and Deviation Index (DI), comply with the international standard IEC 62494-1. In addition, the flat panel detector characteristics described per the FDA *Guidance for the Submission of 510(k)'s for Solid State X-ray Imaging Devices,* (issued on August 6, 1999) fundamentally remains unchanged.

Following the FDA's recommendations of the recently published DRAFT guidance document, *Pediatric Information for X-ray Imaging Device Premarket Notifications* (issued on May 10, 2012), additional laboratory testing data are provided in the submission and an image quality evaluation was performed.

The images using phantoms that mimicked the pediatric subgroups were acquired with each detector type (GOS and CsI) and these images were evaluated by a pediatric radiologist with experience in evaluating patient images and images of pediatric phantoms. Based on the results of this evaluation, Fujifilm concludes that, when used in conjunction with Fujifilm's recommended exposure conditions as a reference, the FDR D-EVO FPD system with both GOS-based and CsI-based panels can provide acceptable diagnostic capability and image quality at reasonably low dose levels typically used for pediatric use. The results of this image quality evaluation and dose assessment are provided in the submission.

IV. SUBSTANTIAL EQUIVALENCE

Fujifilm's FDR D-EVO Flat Panel Detector System (DR-ID600) is substantially equivalent to the following legally marketed devices.

Legally Marketed Device	510(k) #	Clearance date
Wireless/Wired FDR D-EVO flat panel detector system (DR-ID600 w/DR-ID601SE)	K103596	03/29/2011
Wireless/Wired FDR D-EVO flat panel detector system (DR-ID600 w/DR-ID611SE)	K111548	08/30/2011

The Indication For Use (IFU) of the subject device has been updated to specify pediatric and neonatal exams, and corresponding labeling change has occurred to provide the user more information on how to use the subject device in pediatric exams. However no major design, software, and material changes have occurred to support a pediatric indication.

The subject device's detector characteristics including Fujifilm's unique Irradiated Side Sampling (ISS) design delivering high image quality and wireless communication specifications remain unchanged, and the device maintained fundamentally same functional and technical requirements as the predicate devices.

V. CONCLUSION

We concluded the FDR D-EVO Flat Panel Detector System (DR-ID600) is as safe and effective as the legally marketed devices for the proposed Indications For Use based upon the studies summarized above.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

November 25, 2013

Fujifilm Medical Systems USA, Inc.
% Ms. Katherine Y. Choi
Regulatory Affairs Lead
419 West Avenue
STAMFORD CT 06902

Re: K132509
Trade/Device Name: FDR D-EVO Flat Panel Detector System (DR-ID600)
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: MQB
Dated: November 11, 2013
Received: November 12, 2013

Dear Ms. Choi:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

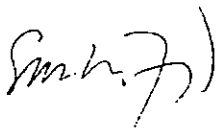
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



for

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
K132509

Device Name
FDR D-EVO Flat Panel Detector System (DR-ID600)

Indications for Use *(Describe)*

The Wireless/Wired FDR D-EVO flat panel detector system is intended to capture for display radiographic images of human anatomy. It is intended for use in general projection radiographic applications including pediatric and neonatal exams wherever conventional film/screen or CR systems may be used. The FDR D-EVO is not intended for mammography, fluoroscopy, tomography, and angiography applications.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*